FORM PTO-1390
REV. 5-93

US DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEYS DOCKET NUMBER
P01,0292

U.S.APPLICATION NO. (if known, see 37 CFR 1.5)
09/914248

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/SE00/00203	**01 February 2000**	**25 February 1999**

TITLE OF INVENTION

IMPLANTABLE TISSUE STIMULATING DEVICE

APPLICANT(S) FOR DO/EO/US

GUNNAR MAGNUSSON

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay.
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of International Application as filed (35 U.S.C. 371(c)(2)) - drawings attached.
   a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2) -
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. §371(c)(3))
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98; **(PTO 1449, Prior Art, Search Report).**
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included. (Separate envelope)
13. ☒ A FIRST preliminary amendment.
    ☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☒ A substitute specification, including red-lined version
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information:
    a. ☒ Request for Approval of Drawing Changes

    B ☒ Express Mail Label EL 843729411US

U.S.APPLICATION NO. (if known, see 37 C.F.R. 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
09/914248	PCT/SE00/00203	R01.0292

518 Rec'd PCT/PTO 24 AUG 2001

17. ☒ The following fees are submitted:	CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 C.F.R. 1.492(a)(1)-(5): Search Report has been prepared by the EPO or JPO $860.00		
International preliminary examination fee paid to USPTO (37 C.F.R. 1.482) $690.00		
No international preliminary examination fee paid to USPTO (37 C.F.R. 1.482) but international search fee paid to USPTO (37 C.F.R. 1.445(a)(2) $760.00		
Neither international preliminary examination fee (37 C.F.R. 1.482) nor international search fee (37 C.F.R. 1.445(a)(2) paid to USPTO $1000.00		
International preliminary examination fee paid to USPTO (37 C.F.R. 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) $100.00		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$860.00	
Surcharge of $130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 C.F.R. 1.492(e)).	$	

Claims	Number Filed		Number Extra	Rate		
Total Claims	14	- 20 =	0	X $18.00	$	
Independent Claims	1	- 3 =	0	X $ 80.00	$	
Multiple Dependent Claims				$270.00 +	$	
				TOTAL OF ABOVE CALCULATIONS =	$860.00	
Reduction by ½ for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 C.F.R. 1.9, 1.27, 1.28)					$	
				SUBTOTAL =	$860.00	
Processing fee of $130.00 for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +					$	
				TOTAL NATIONAL FEE =	860.00	
Fee for recording the enclosed assignment (37 C.F.R. 1.21(h). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). $40.00 per property +						
				TOTAL FEES ENCLOSED =	$860.00	
				Amount to be refunded	$	
				charged	$	

a. ☒ A check in the amount of $860.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of $ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 501519. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 C.F.R. 1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Schiff Hardin & Waite
Patent Department
6600 Sears Tower
Chicago, Illinois 60606
Customer No. 26574

Steven H. Noll
SIGNATURE

Steven H. Noll
NAME

28,982 (Registration No.)

BOX PCT

IN THE UNITED STATES DESIGNATED OFFICE

OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER THE PATENT COOPERATION TREATY-CHAPTER II

REQUEST FOR APPROVAL OF DRAWING CHANGES

APPLICANT: Gunnar Magnusson

ATTORNEY DOCKET NO. P01,0292

INTERNATIONAL APPLICATION NO: PCT/SE00/00203

INTERNATIONAL FILING DATE: February 1, 2000

INVENTION: "IMPLANTABLE TISSUE STIMULATING DEVICE"

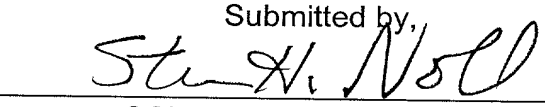
Assistant Commissioner for Patents,

Washington, D.C.

S I R:

Applicant herewith requests approval of the drawing changes in each of Figures 1, 2 and 3, as shown on the drawing copies marked in red attached hereto.

Submitted by,



(Reg. 28,982)

SCHIFF, HARDIN & WAITE
CUSTOMER NO. 26574
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6600 Sears Tower
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Chicago, Illinois 60606
Telephone: 312/258-5790
Attorneys for Applicant.

Fig. 1

(PRIOR ART)

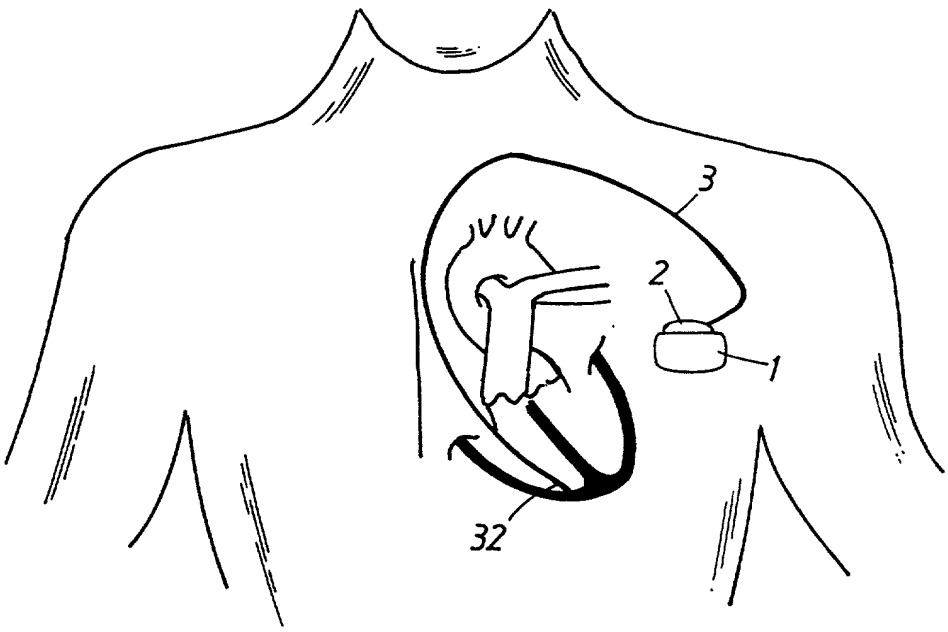


Fig. 2
(PRIOR ART)

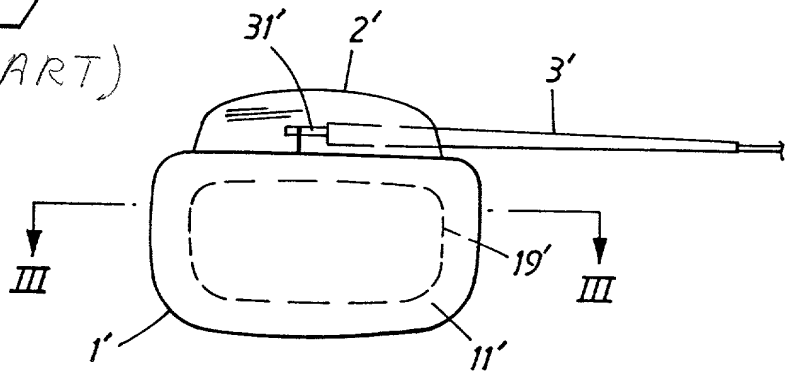


Fig. 3
(PRIOR ART)

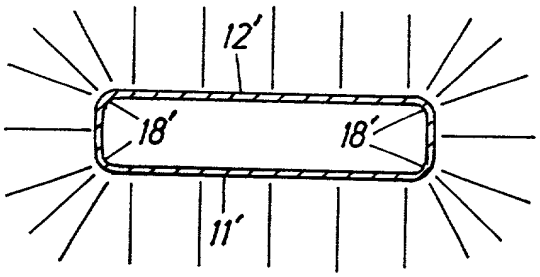


Fig. 4

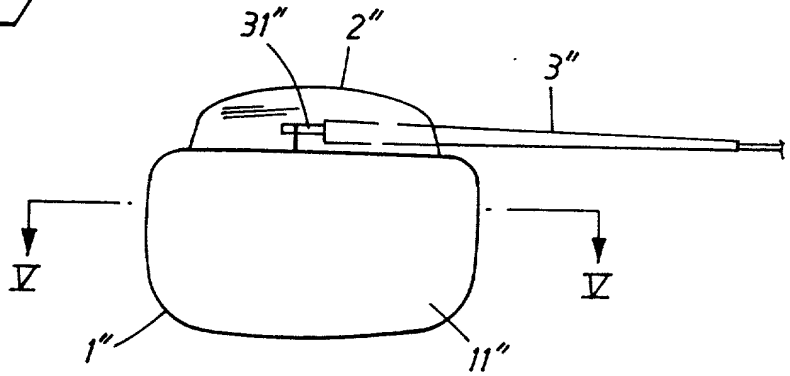
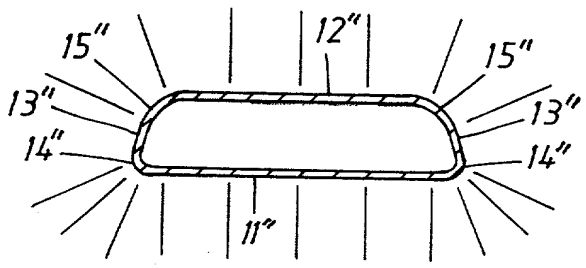


Fig. 5



BOX PCT

IN THE UNITED STATES DESIGNATED OFFICE

OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER THE PATENT COOPERATION TREATY-CHAPTER II

AMENDMENT "A" PRIOR TO ACTION AND SUBMISSION OF SUBSTITUTE SPECIFICATION

APPLICANT: Gunnar Magnusson

ATTORNEY DOCKET NO. P01,0292

INTERNATIONAL APPLICATION NO: PCT/SE00/00203

INTERNATIONAL FILING DATE: February 1, 2000

INVENTION: "IMPLANTABLE TISSUE STIMULATING DEVICE"

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

Applicant herewith amends the above-referenced PCT application as follows, and requests entry of the Amendment prior to examination on the merits in the United States National Examination Phase.

IN THE SPECIFICATION:

Please enter the substitute specification submitted herewith pursuant to 37 C.F.R. §1.125(b). A marked-up version of the substitute specification showing all changes is also submitted herewith. The substitute specification does not contain any new matter.

IN THE DRAWINGS:

Please amend each of Figures 1, 2, and 3 as shown on the drawing copies marked in red, attached to the Request for Approval of Drawing Changes filed simultaneously herewith.

IN THE CLAIMS:

On page 11, cancel "CLAIMS" and substitute:

--**I CLAIM AS MY INVENTION:**-- therefor.

Please cancel claims 1-13 and substitute the following claims therefor:

14. A housing for an implantable tissue stimulating device having an electrode lead with an electrode, said housing being adapted for connection to said electrode lead and said stimulating device generating a voltage between said housing and said electrode, said voltage having an electric field associated therewith, said housing comprising:

a first wall having a generally flat first exterior surface, said first wall being adapted to face the skin of a patient when said housing is implanted;

a second wall having a generally flat second exterior surface; and

a circumferential third wall joining said first wall and said second wall, said third wall being composed of conductive material and adapted for electrical contact with surrounding tissue when said housing is implanted to serve as an electrode, said third circumferential wall having a curved first circumferential wall section connected to said first wall and a curved second circumferential wall section connected to said second wall, said first circumferential wall section having a radius of curvature smaller than a radius of curvature of said second wall section, for curve radii in planes substantially perpendicular to said first surface and said second surface, causing said electric field to have a lower field strength along said second circumferential wall section than along said first circumferential wall section.

15. A housing as claimed in claim 14 wherein said first wall is composed of conductive material and is adapted to be an electrical contact with surrounding tissue for serving as an electrode in combination with the electrode formed by said third wall.

16. A housing as claimed in claim 14 wherein said second wall is composed of conductive material and is adapted to be an electrical contact with surrounding tissue for serving as an electrode in combination with the electrode formed by said third wall.

17. A housing as claimed in claim 14 wherein each of said first circumferential wall section and said second circumferential wall section is circularly curved in said planes.

18. A housing as claimed in claim 17 wherein said first circumferential wall section has a center of curvature along a continuous first curve, and wherein said second circumferential wall section has a center of curvature along a continuous second curve.

19. A housing as claimed in claim 18 wherein said first curve and said second curve are substantially parallel.

20. A housing as claimed in claim 14 wherein the respective curve radii of said first circumferential wall section and said second circumferential wall section in said planes is in a range between 1:2 and 1:6.

21. A housing as claimed in claim 20 wherein said ratio is approximately 1:4.

22. A housing as claimed in claim 14 wherein said first surface is rough.

23. A housing as claimed in claim 14 wherein said first surface is contoured.

24. A housing as claimed in claim 23 wherein said first surface has a plurality of exterior ridges.

25. A housing as claimed in claim 24 wherein each of said ridges has at least one edge with a sharp corner.

26. A housing as claimed in claim 14 wherein said second surface is polished.

IN THE ABSTRACT:

Please add an Abstract as shown on separately numbered page 14 attached hereto.

REMARKS:

The present Amendment makes changes editorial revisions in the specification, drawing, and claims, and adds an Abstract to conform to the present PCT application to the requirements of United States patent practice. The claims submitted herein are considered to have the same scope as original claims 1-13, and no change in any claim has been made for the purpose of distinguishing a claim over the teachings of the prior art of record. Moreover, none of claims submitted herein is considered to narrow any of the original claims.

Early consideration on the merits is respectfully requested.

Submitted by,

(Reg. 28,982)

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Attorneys for Applicant.

ABSTRACT OF THE DISCLOSURE

A housing for an implantable tissue stimulating device is connectable to an electrode lead having an electrode. A portion of the housing also functions as an electrode. The walls of the housing are shaped so that when a voltage is applied between the electrode at the electrode lead, and the housing electrode, the electric field associated with the voltage has a low field strength in regions at which unwanted stimulation of muscles can occur.

SUBSTITUTE SPECIFICATION

TITLE

IMPLANTABLE TISSUE STIMULATING DEVICE

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

The invention relates to a housing for an implantable tissue stimulating device, especially an implantable heart stimulation device.

BACKGROUND OF THE INVENTION AND RELATED ART

Heart stimulation devices for human beings, such as pacemakers are usually implanted in the chest, generally on the left side, a short distance below the clavicle or collar bone. The device will then rest between the pectoralis major and the skin. An electrode lead supplies electric pulses to the heart from the device. The electrode lead includes one or more electrodes, a connector at the proximal end of the electrode lead for connection of the lead to the stimulation device conductor(s) between the connector pin and the electrode(s), one of which typically is located at the distal end of the lead and insulation. The electrode lead is typically passed upwardly over the clavicle and is connected to the heart through a vein adjacent to the clavicle. Usually, the housing of the heart stimulating device is made of conductive material, and electric pulses to the heart are delivered by means of a distal electrode of the electrode lead, being located in the heart in electrical contact with the tissue. The housing is implanted so as to be in electrical contact with the surrounding tissue, and constitutes a second electrode surface. The object is to create an electrical field at the interface of the distal electrode of the electrode lead (stimulation electrode) with the underlying myocardium. However, in a device as described, an electrical field will also be created between the stimulation electrode and the housing. This may, depending on the strength of the field, cause unwanted stimulation of other muscles subjected to

the field, e.g. the pectoralis major. To avoid this effect, parts of the housing can be provided with an insulating cover, e.g. of parylene. Usually the whole housing except for a contact window in a central portion of the side of the housing facing the skin, when implanted, is covered with parylene. In such a case the electric field from the housing will be concentrated to the area of the window.

United States Patent No. 5,480,416 refers to such devices as prior art, and further discloses a pacemaker having two sides covered with parylene, while an edge joining the two sides is uninsulated, and constitutes a contact surface. Thus this pacemaker can be implanted with either of its two sides facing the skin of its carrier.

United States Patent No. 5,658,321 discloses an implantable defibrillator or pulse generator having an electrically conductive housing used as an electrode. The exterior surface of the housing is provided with ridges. Hereby the surface area is increased, and the electrical resistance in the housing/tissue interface is decreased. By the arrangement of sharp corners in connection with the ridges, a further resistance reduction is achieved.

A further casing for a power supply and pulsation control circuitry of a cardiac pacer is disclosed in United States Patent No. 4,094,321. This casing has a substantially flat bottom surface and a shallow dome-shaped top, which tapers to a thin peripheral edge of a small radius of curvature juxtaposed to the bottom and merging curvelinearily therewith. The substantially flat bottom surface can be of metal, epoxy or other suitable inert coating. Further, the bottom surface is provided with a catheter storage means, including rims or grooves. When implanted the casing is located with the dome-shaped top facing the skin, and the substantially flat surface supported by muscles or ribs.

The method widely used today for preventing generation of electric fields in regions where they could cause unwanted stimulation of muscles, by covering portions of a housing, which serves as an electrode, with an insulating material such as parylene, is an effective method. However, it is costly due to the step of the application of the parylene itself and the pre-treatment and after treatment steps.

SUMMARY OF THE INVENTION

It is an object of the invention to provide a housing for an implantable tissue stimulating device which allows the electric fields, which are generated around the housing and which could cause unwanted muscle stimulation, to be eliminated or at least reduced to a safe level, so the risk of unwanted muscle stimulation is eliminated, and which can be produced in a simpler and more cost-effective manufacturing process.

The above object is achieved in accordance with the principles of the present invention in a housing for an implantable tissue stimulating device that has a first wall adapted to face the skin of a patient, when the housing is implanted, the first wall having a first generally flat exterior surface, a second wall having a second generally flat exterior surface and a circumferential third wall joining the first and second walls and having a curved first circumferential wall section connected to the first wall and a curved second circumferential wall section connected to the second wall. The third wall is made of conductive material which is adapted to be in electrical contact with surrounding tissue and to serve as an electrode. The radius of curvature of the first wall section is smaller than the radius of curvature of the second wall section with regard to curve radii in respective planes substantially perpendicular to the first and second flat surfaces. The housing is connectable to an electrode lead, and when a voltage is applied between the housing and the electrode of the electrode lead, an

electric field is obtained having a lower fields strength along the curved second circumferential wall section than along the curved first circumferential wall section.

The inventive housing for an implantable tissue stimulating device, when implanted, acts as an electrode and shaped so as create low strength electric fields in regions where unwanted stimulation of muscles can occur, without the need top cover portions of the housing with an insulating layer.

By the arrangement of a curved circumferential first wall section connected to a first wall having a generally flat exterior surface, and a curved circumferential second wall section connected to a second wall having a generally flat exterior surface, where the first wall section has a smaller radius of curvature than the second wall section a favorable electric field distribution around the housing is obtained.

Roughening the surface or providing the surface with ridges or irregularities can increase the electrical field at the region of the wall facing the skin.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 schematically shows a pacemaker implanted in a patient.

Figure 2 is a schematic view of a prior art pacemaker.

Figure 3 shows a cross section taken at III-III in FIG 2.

Figure 4 is a schematic view of an embodiment of a housing for an implantable tissue stimulating device according to the invention.

Figure 5 shows a cross section taken at V-V in FIG 4.

Figure 6 is a schematic view of an alternative surface structure of the first wall of the housing of the invention.

Figure 7 shows a cross section taken at VII-VII in FIG 6.

Figure 8 is a schematic view of a further alternative surface structure of the first wall of the housing of the invention.

Figure 9 shows a cross section taken at IX-IX in FIG 8.

DESCRIPTION OF PREFERRED EMBODIMENTS

A conventional placement of a pacemaker implanted in a patient is shown. A housing 1 for a pulse generator is implanted on the left side of the chest. The housing is conductive, made of a bio-compatible material such as titanium, and hermetically sealed against intrusion of body fluids and tissue when implanted. On top of the housing a header 2 is arranged. The header is made of transparent epoxy resin, and is molded onto the housing. The header includes a female portion of an electrical connector coupled to the circuits of the pulse generator. An electrode lead 3 includes at its proximal end a male connector 31 (connector pin, not shown) for electrical connection with said female connector. At the distal end the electrode lead 3 is provided with a stimulation electrode 32, which is located in the heart in electrical contact with the tissue. A stimulation pulse generated by the pulse generator will be applied between the electrode 32 and the housing 1, which also acts as an electrode. The electrode 32 may also serve as a sensing electrode, and the housing 1 then serves as the second sensing electrode. Between the male connector 31 and the electrode 32 the lead 3 includes an electrically conductive wire provided with insulation.

Alternatively the lead may have an additional electrode, preferably also located in the heart. In such a case, sensing is preferably performed by means of the electrodes of the lead, and the number of insulated wires of the lead will be the same as the number of the electrodes.

In FIG. 2, the housing and a proximal lead portion of a prior art device to be implanted as shown in FIG 1, is shown in an enlarged view. The housing 1' has a first wall 11' having a first generally flat exterior surface. The housing is adapted to be implanted with this first surface facing the skin of the patient.

FIG. 3 is a cross section taken at III-III in FIG. 2, with the housed parts and components omitted, for simplicity. Opposed to the first wall 11', a second wall 12' having a second generally flat exterior surface, is provided. The first and second walls 11', 12' are joined by a connecting wall, and corners 18' are formed where the connecting wall joins the first wall 11' and the second wall 12', respectively. When a voltage is applied between the electrode of the lead and the housing, an electric field will bee generated around the housing. This is illustrated with schematic field lines. Along the corners 18' the field will exhibit strong field concentrations, leading to high current densities in the surrounding tissue and possibly to unwanted stimulation of muscles. To prevent this, prior art devices have been provided with an insulating parylene coating of the whole housing except for a central portion of the surface facing the skin of the patient, as mentioned above. This portion or window 19' is shown with broken lines in FIG. 2.

An embodiment of a housing for an implantable tissue stimulating device according to the invention is shown in FIG. 4, and a cross section taken at V-V thereof is shown in FIG. 5.

This device is also adapted to be implanted as shown in FIG 1. Also in FIG. 5 the housed parts and components are omitted, for simplicity. A housing 1" has a first wall 11", having a first generally flat exterior surface, and a second wall 12" having a second generally flat exterior surface. The first and second walls 11", 12" are joined by a third circumferential wall 13". The third wall 13" has a curved circumferential first wall section 14" that is connected to the first wall 11" around its periphery. The third wall 13" further has a curved circumferential second wall section 15" that is connected to the second wall 12".

On top of the housing 1" a header 2" is provided. It is of the above mentioned kind, made of transparent epoxy, and molded onto the housing 1". The header 2" could be molded to the housing 1" so as to cover an adjacent portion of the second wall section 15" and possibly also an adjacent portion of the first wall section 14".

The first wall 11", second wall 12" and third wall 13" are all made of an electrically conductive material, such as titanium, and the housing is hermetically sealed.

As seen in FIG. 5 the radii of curvature of the first wall section 14" and the second wall section 15", taken in a plane perpendicular to the first 11" and second 12" walls, are different. The first wall section 14" has a smaller radius of curvature, whereas the second wall section 15" has a greater radius of curvature. The ratio between the curve radii is in the range of 1:2-1:6, and preferably around 1:4. When discussing the radii of curvature of the wall sections, it is assumed that the thicknesses of the wall sections are uniform. However, this is not necessary, and in cases where a curve radius of a wall section is difficult to define it is referred to the exterior surface of the actual wall section.

The condition that the first wall section 14" has smaller radius of curvature than the second wall section 15" is generally valid for all planes through and perpendicular to the first and second walls 11", 12". Preferably the ratio between the radii of curvature is the same all the way along the third wall 13". However, in the region of the header, the desired effect could be obtained due to the insulating properties of the header material, especially when the header covers a portion of the second wall section 15". In such a case the relation between the radii of curvature at this location can be somewhat different than mentioned above, without departing from the spirit of the invention.

The first and second wall sections 14", 15" are circularly curved in said planes. For a housing shown in FIG. 5, having a thickness of e.g. about 6 mm, i.e. the distance between the exterior surfaces of the first and second walls, the radii of curvature could bee 1 mm and 4 mm for the first and second wall sections 14", 15", respectively. However, the wall sections may be curved in other shapes, e.g. partially elliptical. It is important that the curve of the first wall section 14" is sharper than the curve of the second wall section 15". For housing thicknesses of e.g. 8 and 9 mm, the radii of curvature could be the same as for the 6 mm case. Practically the smallest radius of curvature (of the first wall section 14") should not be smaller than about 1 mm, even if it could be a sharp corner.

The housing shown in FIGS. 4 and 5 is adapted to be implanted in a patient with the first wall 11" facing the skin. When in use, and when pulses are applied to the stimulation electrode(s) of the electrode lead, an electric field is generated around the housing 1", which is coupled to the pulse generator, and acts as an electrode. By the arrangement of the curved circumferential first wall section 14" and the curved

circumferential second wall section 15" where the first wall section 14" has smaller radius of curvature than the second wall section 15" a favourable electric field distribution around the housing is obtained. As illustrated in FIG.5 with schematic field lines, there will be a lower field concentration in the region around the more smoothly curved second wall section 15" than in the region around the more sharply curved first wall section 14". Due to the weak electric field in the region around the curved second wall section 15" the current density here will be low, and the risk of unwanted stimulation is eliminated or at least heavily reduced. In the region around the curved first wall section 14", on the other hand, the electric field will be relatively strong, resulting in a relatively high current density in the adjacent tissue. This is advantageous since in this region there are no muscles that could be stimulated, and the currents can be distributed in a favorable way.

In order to smoothen the exterior surfaces of the second wall and second wall section, they can be polished. Thus small field concentrating irregularities of the surfaces are removed. This will homogenize the field, and possibly also reduce it. For the exterior surface of the first wall and possibly also for the first wall section the contrary is desired. Therefore the generally flat exterior surface of the first wall and possibly also the first wall section could be blasted in order to achieve a relatively rough surface. Besides a concentration of a field, a decreased electrical resistance in the housing/tissue interface around this wall and wall section is also achieved. Grinding, abrading, brushing, or chemically etching the surface e.g. to generate sharp peaks, which may be elongated ridges, could also form the roughness or irregularities of the surface(s) or individual pointed peaks.

FIG 6 shows the exterior surface of the first wall 11" being

roughened, textured or contoured. The exterior surface of the first wall 11" is provided with an array of grooves 17". The grooves 17" alternate with an array of ridges 16", each of which proceeds between and defines adjacent grooves. The grooves can be formed as mentioned above or by cutting, milling, or stamping. As an example, the grooves can be cut to a depth of 0.25 mm and a width of 0.40 mm, while the ridges have a width of 0.40 mm.

In FIG 7 a cross section taken at VII-VII in FIG 6, is shown. Here, the ridges 16" and grooves 17" are shown somewhat enlarged. The ridges are shown to be rectangular in cross section, however, they could have V-shaped cross-section.

FIG 8 shows an alternative shape of the grooves 17" and ridges 16". Here they are formed in an annular and concentric pattern. Other patterns are also possible, e.g. elliptic or spiral. In Fig 9 a cross section taken at IX-IX in figure 8, is shown. Also here, the ridges 16" and grooves 17" are shown somewhat enlarged. The cross-sectional shapes of the grooves and ridges could be the same as in the embodiment of FIGS 6 and 7.

In the embodiments of the invention above, the first 11", second 12" and third 13" walls are all made of an electrically conductive material that is to be in contact with surrounding tissue. However the third wall 13" could be made of an electrically conductive material, and the second wall 12" and possibly also the first wall 11" made of a non-conductive material, or alternatively covered with an insulating layer.

The curve radii of the irregularities or ridges are very small, at least smaller than 1 mm, and they could be as small as 0.1 mm, or smaller.

Although the invention is described by means of the above examples, naturally, many variations are possible within the scope of the invention.

MARKED-UP COPY

TITLE

IMPLANTABLE TISSUE STIMULATING DEVICE

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

The invention relates to a housing for an implantable tissue stimulating device, especially an implantable heart stimulation device.

BACKGROUND OF THE INVENTION AND RELATED ART

Heart stimulation devices for human beings, such as pacemakers are usually implanted in the chest, [mostly] generally on the left side,
a short distance below the clavicle or collar bone. The device will then rest between the pectoralis major and the skin. An electrode lead supplies electric pulses to the heart from the device. The electrode lead includes[:] one or more electrodes[;], a connector[,] at the proximal end of the electrode lead[,] for connection of the lead to the stimulation device[;] conductor(s) between the connector pin and the electrode(s), [whereof] one of which typically is located at the distal end of the lead[;] and[,] insulation. The electrode lead is typically passed upwardly over the clavicle and is connected to the heart through a vein adjacent to the clavicle. Usually, the housing of the heart stimulating device is made of conductive material, and electric pulses to the heart are delivered by means of a distal electrode of the electrode lead, being located in the heart in electrical contact with the tissue. The housing is implanted so as to be in electrical contact with the surrounding tissue, and constitutes a second electrode surface. The object is to create an electrical field at the interface of the distal electrode of the electrode lead (stimulation electrode) with the underlying myocardium. However, in a device as described, an electrical field will also be created between the stimulation electrode and the housing. This may, depending on the strength of the

field, cause unwanted stimulation of other muscles subjected to the field, e.g. the pectoralis major. To avoid this effect, parts of the housing can be provided with an insulating cover, e.g. of parylene. Usually the whole housing except for a contact window in a central portion of the side of the housing facing the skin, when implanted, is covered with parylene. In such a case the electric field from the housing will be concentrated to the area of the window.

[US-A-S 480 416] United States Patent No. 5,480,416 refers to such devices as prior art, and further discloses a pacemaker having two sides covered with parylene, while an edge joining the two sides is uninsulated, and constitutes a contact surface. Thus this pacemaker can be implanted with either of its two sides facing the skin of its carrier.

[In US-A- 5 658 321 there is disclosed] United States Patent No. 5,658,321 discloses an implantable defibrillator or pulse generator having an electrically conductive housing used as an electrode. The exterior surface of the housing is provided with ridges. Hereby the surface area is increased, and the electrical resistance in the housing/tissue interface is decreased. By the arrangement of sharp corners in connection with the ridges, a further resistance reduction is achieved.

A further casing for a power supply and pulsation control circuitry of a cardiac pacer is disclosed in United States Patent No. 4,094,321 [US-A 4 094 321]. This casing [comprises] has a substantially flat bottom surface and a shallow dome-shaped top, which tapers [down] to a thin peripheral edge of a small radius of curvature juxtaposed to the bottom and merging curvelinearly therewith. The substantially flat bottom surface can be of metal, epoxy or other suitable inert coating. Further, [said] the bottom surface is provided with a catheter storage means, including rims or grooves. When implanted the casing is located with the dome-shaped

top facing the skin, and the substantially flat surface supported by muscles or ribs.

The method widely used today[,] for preventing generation of electric fields in regions where they could cause unwanted stimulation of muscles, by covering portions of a housing, which serves as an electrode, with an insulating material such as parylene, is an effective method. However, it is costly due to the step of the application of the parylene itself and the pre-treatment and after treatment steps.

SUMMARY OF THE INVENTION

It is an object of the invention to provide a housing for an implantable tissue stimulating device [where] which allows the electric fields, which are generated around the housing and which could cause unwanted muscle stimulation, [could] to be eliminated[,] or at least reduced to a safe level, [where] so the risk of unwanted muscle stimulation is eliminated, and which [housing] can be produced in a simpler and more cost-effective manufacturing process.

[A device according to the features of claim 1 achieves this.]

The above object is achieved in accordance with the principles of the present invention in a housing for an implantable tissue stimulating device that has a first wall adapted to face the skin of a patient, when the housing is implanted, the first wall having a first generally flat exterior surface, a second wall having a second generally flat exterior surface and a circumferential third wall joining the first and second walls and having a curved first circumferential wall section connected to the first wall and a curved second circumferential wall section connected to the second wall. The third wall is made of conductive material which is adapted to be in electrical contact with surrounding tissue and to serve as an electrode. The radius of curvature of the first wall section is

smaller than the radius of curvature of the second wall section with regard to curve radii in respective planes substantially perpendicular to the first and second flat surfaces. The housing is connectable to an electrode lead, and when a voltage is applied between the housing and the electrode of the electrode lead, an electric field is obtained having a lower fields strength along the curved second circumferential wall section than along the curved first circumferential wall section.

[By these features, a] The inventive housing for an implantable tissue stimulating device [is provided, where], when implanted, [the housing is acting] acts as an electrode and shaped so as create low strength electric fields in regions where unwanted stimulation of muscles can occur, without the need [of covering] top cover portions of the housing with an insulating layer.

By the arrangement of a curved circumferential first wall section connected to a first wall having a generally flat exterior surface, and a curved circumferential second wall section connected to a second wall having a generally flat exterior surface, where the first wall section has a smaller radius of curvature than the second wall section a [favourable] favorable electric field distribution around the housing is obtained.

Roughening the surface or providing the surface with ridges or irregularities can increase the electrical field at the region of the wall facing the skin.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 schematically shows a pacemaker implanted in a patient.

Figure 2 is a schematic view of a prior art pacemaker.

Figure 3 shows a cross section taken at III-III in FIG 2.

Figure 4 is a schematic view of an embodiment of a housing for an implantable tissue stimulating device according to the invention.

Figure 5 shows a cross section taken at V-V in FIG 4.

Figure 6 is a schematic view of an alternative surface structure of the first wall of the housing of the invention.

Figure 7 shows a cross section taken at VII-VII in FIG 6.

Figure 8 is a schematic view of a further alternative surface structure of the first wall of the housing of the invention.

Figure 9 shows a cross section taken at IX-IX in [figure] FIG 8.

DESCRIPTION OF PREFERRED EMBODIMENTS

[With reference to FIG 1, a] A conventional placement of a pacemaker implanted in a patient is shown. A housing 1 for a pulse generator is implanted on the left side of the chest. The housing is conductive, made of a bio-compatible material such as titanium, and hermetically sealed against intrusion of body fluids and tissue when implanted. On top of the housing a header 2 is arranged. The header is made of transparent epoxy resin, and is [moulded] molded onto the housing. The header includes a female portion of an electrical connector coupled to the circuits of the pulse generator. An electrode lead 3 includes at its proximal end a male connector 31 (connector pin, not shown) for electrical connection with said female connector. At the distal end the electrode lead 3 is provided with a stimulation electrode 32, which is located in the heart in electrical contact with the tissue. A stimulation pulse

generated by the pulse generator will be applied between the electrode 32 and the housing 1, which also acts as an electrode. The electrode 32 may also serve as a sensing electrode, and the housing 1 then serves as the second sensing electrode. Between the male connector 31 and the electrode 32 the lead 3 includes an electrically conductive wire provided with insulation.

Alternatively the lead may [comprise] have an additional electrode, preferably also located in the heart. In such a case, [the] sensing is preferably performed by means of the electrodes of the lead, and the number of insulated wires of the lead will be the same as the number of the electrodes.

In FIG. 2, the housing and a proximal lead portion[,] of a prior art device to be implanted as shown in FIG 1, is shown in an enlarged view. The housing 1' has a first wall 11' having a first generally flat exterior surface. The housing is adapted to be implanted with this first surface facing the skin of the patient.

FIG. 3 is a cross section taken at III-III in FIG. 2, with the housed parts and components omitted, for simplicity. Opposed to the first wall 11', a second wall 12' having a second generally flat exterior surface, is provided. The first and second walls 11', 12' are joined by a connecting wall, and corners 18' are formed where the connecting wall joins the first wall 11' and the second wall 12', respectively. When a voltage is applied between the electrode of the lead and the housing, an electric field will bee generated around the housing. This is illustrated with schematic field lines. Along the corners 18' the field will exhibit strong field concentrations, leading to high current densities in the surrounding tissue and possibly to unwanted stimulation of muscles. To prevent this, prior art

devices have been provided with an insulating parylene coating of the whole housing except for a central portion of the surface facing the skin of the patient, as mentioned above. This portion or window 19' is shown with broken lines in FIG. 2.

An embodiment of a housing for an implantable tissue stimulating device according to the invention is shown in FIG. 4, and a cross section taken at V-V thereof is shown in FIG. 5. This device is also adapted to be implanted as shown in FIG 1. Also in FIG. 5 the housed parts and components are omitted, for simplicity. A housing 1" [comprises] has a first wall 11", having a first generally flat exterior surface, and a second wall 12" having a second generally flat exterior surface. The first and second walls 11", 12" are joined by a third circumferential wall 13". The third wall 13" [comprises] has a curved circumferential first wall section 14" that is connected to the first wall 11" around its periphery. The third wall 13" further [comprises] has a curved circumferential second wall section 15" that is connected to the second wall 12".

On top of the housing 1" a header 2" is provided. It is of the above mentioned kind, made of transparent epoxy, and [moulded] molded onto the housing 1". The header 2" could be [moulded] molded to the housing 1" so as to cover an adjacent portion of the second wall section 15" and possibly also an adjacent portion of the first wall section 14".

The first wall 11", second wall 12" and third wall 13" [walls] are all made of an electrically conductive material, such as titanium, and the housing is hermetically sealed.

As seen in FIG. 5 the radii of curvature of the first wall section 14" and the second wall section 15", taken in a plane perpendicular to the first 11" and second 12" walls, are

different. The first wall section 14" has a smaller radius of curvature, whereas the second wall section 15" has a greater radius of curvature. The ratio between the curve radii is in the range of 1:2-1:6, and preferably around 1:4. When discussing the radii of curvature of the wall sections, it is assumed that the thicknesses of the wall sections are uniform. However, this is not necessary, and in cases where a curve radius of a wall section is difficult to define it is referred to the exterior surface of the actual wall section.

The condition that the first wall section 14" has smaller radius of curvature than the second wall section 15" is generally valid for all planes through and perpendicular to the first and second walls 11", 12". Preferably the ratio between the radii of curvature is the same all the way along the third wall 13". However, in the region of the header, the desired effect could be obtained due to the insulating properties of the header material, especially when the header covers a portion of the second wall section 15". In such a case the relation between the radii of curvature at this location can be somewhat different than mentioned above, without departing from the spirit of the invention.

The first and second wall sections 14", 15" are circularly curved in said planes. For a housing shown in FIG. 5, having a thickness of e.g. about 6 mm, i.e. the distance between the exterior surfaces of the first and second walls, the radii of curvature could bee 1 mm and 4 mm for the first and second wall sections 14", 15", respectively. However, the wall sections may be curved in other shapes, e.g. partially elliptical. [What's] It is important [is] that the curve of the first wall section 14" is sharper than the curve of the second wall section 15". For housing thicknesses of e.g. 8 and 9 mm, the radii of curvature could be the same as for the 6 mm case. Practically the smallest radius of curvature (of the first wall section 14")

should not be smaller than about 1 mm, even if it could be a sharp corner.

The housing shown in FIGS. 4 and 5 is adapted to be implanted in a patient with the first wall 11" facing the skin. When in use, and when pulses are applied to the stimulation electrode(s) of the electrode lead, an electric field is generated around the housing 1", which is coupled to the pulse generator, and acts as an electrode. By the arrangement of the curved circumferential first wall section 14" and the curved circumferential second wall section 15" where the first wall section 14" has smaller radius of curvature than the second wall section 15" a favourable electric field distribution around the housing is obtained. As illustrated in FIG.5 with schematic field lines, there will be a lower field concentration in the region around the more smoothly curved second wall section 15" than in the region around the more sharply curved first wall section 14". Due to the weak electric field in the region around the curved second wall section 15" the current density here will be low, and the risk of unwanted stimulation is eliminated or at least heavily reduced. In the region around the curved first wall section 14", on the other hand, the electric field will be relatively strong, resulting in a relatively high current density in the adjacent tissue. This is advantageous since in this region there are no muscles that could be stimulated, and the currents can be distributed in a [favourable] favorable way.

In order to smoothen the exterior surfaces of the second wall and second wall section, they can be polished. [Hereby,] Thus small field concentrating irregularities of the surfaces are removed. This will [even out] homogenize the field, and possibly also reduce it. For the exterior surface of the first wall and possibly also for the first wall section the contrary is desired. Therefore the generally flat exterior surface of the first wall and

possibly also the first wall section could be blasted in order to achieve a relatively rough surface. Besides a concentration of a field, a decreased electrical resistance in the housing/tissue interface around this wall and wall section is also achieved. Grinding, abrading, brushing, or chemically etching the surface e.g. to generate sharp peaks, which may be elongated ridges, could also form the roughness or irregularities of the surface(s) or individual pointed peaks.

FIG 6 shows the exterior surface of the first wall 11" being roughened, textured or contoured. The exterior surface of the first wall 11" is provided with an array of grooves 17". The grooves 17" alternate with an array of ridges 16", each of which [stands] proceeds between and defines adjacent grooves. The grooves can be formed as mentioned above or by cutting, milling, or stamping. As an example, the grooves can be cut to a depth of 0.25 mm and a width of 0.40 mm, while the ridges have a width of 0.40 mm.

In FIG 7 a cross section taken at VII-VII in FIG 6, is shown. Here, the ridges 16" and grooves 17" are shown somewhat enlarged. The ridges are shown to be rectangular in cross section[. However], however, they could have V-shaped cross-section.

FIG 8 shows an alternative shape of the grooves 17" and ridges 16". Here they are formed in an annular and concentric pattern. Other patterns are also possible, e.g. elliptic or spiral. In Fig 9 a cross section taken at IX-IX in figure 8, is shown. Also here, the ridges 16" and grooves 17" are shown somewhat enlarged. The cross-sectional shapes of the grooves and ridges could be the same as in the embodiment of FIGS 6 and 7.

In the embodiments of the invention above, the first 11", second 12" and third 13" walls are all made of an electrically conductive material that is to be in contact with surrounding

tissue. However the third wall 13" could be made of an electrically conductive material, and the second wall 12" and possibly also the first wall 11" made of a non-conductive material, or alternatively covered with an insulating layer.

The curve radii of the irregularities or ridges are very small, at least smaller than 1 mm, and they could be as small as 0.1 mm, or smaller.

Although the invention is described by means of the above examples, naturally, many variations are possible within the scope of the invention.

IMPLANTABLE TISSUE STIMULATING DEVICE

FIELD OF THE INVENTION

The invention relates to a housing for an implantable tissue stimulating device, especially an implantable heart stimulation device.

BACKGROUND OF THE INVENTION AND RELATED ART

Heart stimulation devices for human beings, such as pacemakers are usually implanted in the chest, mostly on the left side, a short distance below the clavicle or collar bone. The device will then rest between the pectoralis major and the skin. An electrode lead supplies electric pulses to the heart from the device. The electrode lead includes: one or more electrodes; a connector, at the proximal end of the electrode lead, for connection of the lead to the stimulation device; conductor(s) between the connector pin and the electrode(s) whereof one typically is located at the distal end of the lead; and, insulation. The electrode lead is typically passed upwardly over the clavicle and is connected to the heart through a vein adjacent to the clavicle. Usually, the housing of the heart stimulating device is made of conductive material, and electric pulses to the heart are delivered by means of a distal electrode of the electrode lead, being located in the heart in electrical contact with the tissue. The housing is implanted so as to be in electrical contact with the surrounding tissue, and constitutes a second electrode surface. The object is to create an electrical field at the interface of the distal electrode of the electrode lead (stimulation electrode) with the underlying myocardium. However, in a device as described, an electrical field will also be created between the stimulation electrode and the housing. This may, depending on the strength of the field, cause unwanted stimulation of other muscles subjected to

the field, e.g. the pectoralis major. To avoid this effect, parts of the housing can be provided with an insulating cover, e.g. of parylene. Usually the whole housing except for a contact window in a central portion of the side of the housing facing the skin, when implanted, is covered with parylene. In such a case the electric field from the housing will be concentrated to the area of the window.

US-A-5 480 416 refers to such devices as prior art, and further discloses a pacemaker having two sides covered with parylene, while an edge joining the two sides is uninsulated, and constitutes a contact surface. Thus this pacemaker can be implanted with either of its two sides facing the skin of its carrier.

In US-A- 5 658 321 there is disclosed an implantable defibrillator or pulse generator having an electrically conductive housing used as an electrode. The exterior surface of the housing is provided with ridges. Hereby the surface area is increased, and the electrical resistance in the housing/tissue interface is decreased. By the arrangement of sharp corners in connection with the ridges, a further resistance reduction is achieved.

A further casing for a power supply and pulsation control circuitry of a cardiac pacer is disclosed in US-A 4 094 321. This casing comprises a substantially flat bottom surface and a shallow dome-shaped top, which tapers down to a thin peripheral edge of a small radius of curvature juxtaposed to the bottom and merging curvelinearily therewith. The substantially flat bottom surface can be of metal, epoxy or other suitable inert coating. Further, said bottom surface is provided with a catheter storage means, including rims or grooves. When implanted the casing is located with the dome-shaped top facing

the skin, and the substantially flat surface supported by muscles or ribs.

The method widely used today, for preventing generation of electric fields in regions where they could cause unwanted stimulation of muscles, by covering portions of a housing, which serves as an electrode, with an insulating material such as parylene, is an effective method. However, it is costly due to the step of the application of the parylene itself and the pre-treatment and after treatment steps.

SUMMARY OF THE INVENTION

It is an object of the invention to provide a housing for an implantable tissue stimulating device where the electric fields, which are generated around the housing and could cause unwanted muscle stimulation, could be eliminated, or at least reduced to a safe level, where the risk of unwanted muscle stimulation is eliminated, which housing can be produced in a simpler and more cost-effective manufacturing process.

A device according to the features of claim 1 achieves this.

By these features, a housing for an implantable tissue stimulating device is provided, where, when implanted, the housing is acting as an electrode and shaped so as create low strength electric fields in regions where unwanted stimulation of muscles can occur, without the need of covering portions of the housing with an insulating layer.

By the arrangement of a curved circumferential first wall section connected to a first wall having a generally flat exterior surface, and a curved circumferential second wall section connected to a second wall having a generally flat exterior surface, where the first wall section has smaller

radius of curvature than the second wall section a favourable electric field distribution around the housing is obtained.

Roughening the surface or providing the surface with ridges or irregularities can increase the electrical field at the region of the wall facing the skin.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 schematically shows a pacemaker implanted in a patient.

Figure 2 is a schematic view of a prior art pacemaker.

Figure 3 shows a cross section taken at III-III in FIG 2.

Figure 4 is a schematic view of an embodiment of a housing for an implantable tissue stimulating device according to the invention.

Figure 5 shows a cross section taken at V-V in FIG 4.

Figure 6 is a schematic view of an alternative surface structure of the first wall of the housing of the invention.

Figure 7 shows a cross section taken at VII-VII in FIG 6.

Figure 8 is a schematic view of a further alternative surface structure of the first wall of the housing of the invention.

Figure 9 shows a cross section taken at IX-IX in figure 8.

DESCRIPTION OF PREFERRED EMBODIMENTS

With reference to FIG 1, a conventional placement of a pacemaker implanted in a patient is shown. A housing 1 for a pulse generator is implanted on the left side of the chest. The housing is conductive, made of a bio-compatible material such as titanium, and hermetically sealed against intrusion of body fluids and tissue when implanted. On top of the housing a header 2 is arranged. The header is made of transparent epoxy resin, and is moulded onto the housing. The header includes a female portion of an electrical connector coupled to the circuits of the pulse generator. An electrode lead 3 includes at its proximal end a male connector 31 (connector pin, not shown) for electrical connection with said female connector. At the distal end the electrode lead 3 is provided with a stimulation electrode 32, which is located in the heart in electrical contact with the tissue. A stimulation pulse generated by the pulse generator will be applied between the electrode 32 and the housing 1, which also acts as an electrode. The electrode 32 may also serve as a sensing electrode, and the housing 1 then serves as the second sensing electrode. Between the male connector 31 and the electrode 32 the lead 3 includes an electrically conductive wire provided with insulation.

Alternatively the lead may comprise an additional electrode, preferably also located in the heart. In such a case, the sensing is preferably performed by means of the electrodes of the lead, and the number of insulated wires of the lead will be the same as the number of the electrodes.

In FIG. 2, the housing and a proximal lead portion, of a prior art device to be implanted as shown in FIG 1, is shown in an enlarged view. The housing 1' has a first wall 11' having a first generally flat exterior surface. The housing is adapted to be implanted with this first surface facing the skin of the patient.

FIG. 3 is a cross section taken at III-III in FIG. 2, with the housed parts and components omitted, for simplicity. Opposed to the first wall 11', a second wall 12' having a second generally flat exterior surface, is provided. The first and second walls 11', 12' are joined by a connecting wall, and corners 18' are formed where the connecting wall joins the first wall 11' and the second wall 12', respectively. When a voltage is applied between the electrode of the lead and the housing, an electric field will bee generated around the housing. This is illustrated with schematic field lines. Along the corners 18' the field will exhibit strong field concentrations, leading to high current densities in the surrounding tissue and possibly to unwanted stimulation of muscles. To prevent this, prior art devices have been provided with an insulating parylene coating of the whole housing except for a central portion of the surface facing the skin of the patient, as mentioned above. This portion or window 19' is shown with broken lines in FIG. 2.

An embodiment of a housing for an implantable tissue stimulating device according to the invention is shown in FIG. 4, and a cross section taken at V-V thereof is shown in FIG.5. This device is also adapted to be implanted as shown in FIG 1. Also in FIG. 5 the housed parts and components are omitted, for simplicity. A housing 1" comprises a first wall 11", having a first generally flat exterior surface, and a second wall 12" having a second generally flat exterior surface. The first and second walls 11", 12" are joined by a third circumferential wall 13". The third wall 13" comprises a curved circumferential first wall section 14" that is connected to the first wall 11" around its periphery. The third wall 13" further comprises a

curved circumferential second wall section 15" that is connected to the second wall 12".

On top of the housing 1" a header 2" is provided. It is of the above mentioned kind, made of transparent epoxy, and moulded onto the housing 1". The header 2" could be moulded to the housing 1" so as to cover an adjacent portion of the second wall section 15" and possibly also an adjacent portion of the first wall section 14".

The first 11", second 12" and third 13" walls are all made of an electrically conductive material, such as titanium, and the housing is hermetically sealed.

As seen in FIG. 5 the radii of curvature of the first wall section 14" and the second wall section 15", taken in a plane perpendicular to the first 11" and second 12" walls are different. The first wall section 14" has a smaller radius of curvature, whereas the second wall section 15" has a greater radius of curvature. The ratio between the curve radii is in the range of 1:2-1:6, and preferably around 1:4. When discussing the radii of curvature of the wall sections, it is assumed that the thicknesses of the wall sections are uniform. However, this is not necessary, and in cases where a curve radius of a wall section is difficult to define it is referred to the exterior surface of the actual wall section.

The condition that the first wall section 14" has smaller radius of curvature than the second wall section 15" is generally valid for all planes through and perpendicular to the first and second walls 11", 12". Preferably the ratio between the radii of curvature is the same all the way along the third wall 13". However, in the region of the header, the desired

effect could be obtained due to the insulating properties of the header material, especially when the header covers a portion of the second wall section 15". In such a case the relation between the radii of curvature at this location can be somewhat different than mentioned above, without departing from the spirit of the invention.

The first and second wall sections 14", 15" are circularly curved in said planes. For a housing shown in FIG. 5, having a thickness of e.g. about 6 mm, i.e. the distance between the exterior surfaces of the first and second walls, the radii of curvature could bee 1 mm and 4 mm for the first and second wall sections 14", 15", respectively. However, the wall sections may be curved in other shapes, e.g. partially elliptical. What's important is that the curve of the first wall section 14" is sharper than the curve of the second wall section 15". For housing thicknesses of e.g. 8 and 9 mm, the radii of curvature could be the same as for the 6 mm case. Practically the smallest radius of curvature (of the first wall section 14") should not be smaller than about 1 mm, even if it could be a sharp corner.

The housing shown in FIGS. 4 and 5 is adapted to be implanted in a patient with the first wall 11" facing the skin. When in use, and when pulses are applied to the stimulation electrode(s) of the electrode lead, an electric field is generated around the housing 1", which is coupled to the pulse generator, and acts as an electrode. By the arrangement of the curved circumferential first wall section 14" and the curved circumferential second wall section 15" where the first wall section 14" has smaller radius of curvature than the second wall section 15" a favourable electric field distribution around the housing is obtained. As illustrated in FIG.5 with

schematic field lines, there will be a lower field concentration in the region around the more smoothly curved second wall section 15" than in the region around the more sharply curved first wall section 14". Due to the weak electric field in the region around the curved second wall section 15" the current density here will be low, and the risk of unwanted stimulation is eliminated or at least heavily reduced. In the region around the curved first wall section 14", on the other hand, the electric field will be relatively strong, resulting in a relatively high current density in the adjacent tissue. This is advantageous since in this region there are no muscles that could be stimulated, and the currents can be distributed in a favourable way.

In order to smoothen the exterior surfaces of the second wall and second wall section, they can be polished. Hereby, small field concentrating irregularities of the surfaces are removed. This will even out the field, and possibly also reduce it. For the exterior surface of the first wall and possibly also for the first wall section the contrary is desired. Therefore the generally flat exterior surface of the first wall and possibly also the first wall section could be blasted in order to achieve a relatively rough surface. Besides a concentration of a field, a decreased electrical resistance in the housing/tissue interface around this wall and wall section is also achieved. Grinding, abrading, brushing, or chemically etching the surface e.g. to generate sharp peaks, which may be elongated ridges, could also form the roughness or irregularities of the surface(s) or individual pointed peaks.

FIG 6 shows the exterior surface of the first wall 11" being roughened, textured or contoured. The exterior surface of the first wall 11" is provided with an array of grooves 17". The grooves 17" alternate with an array of ridges 16", each of

which stands between and defines adjacent grooves. The grooves can be formed as mentioned above or by cutting, milling, or stamping. As an example, the grooves can be cut to a depth of 0.25 mm and a width of 0.40 mm, while the ridges have a width of 0.40 mm.

In FIG 7 a cross section taken at VII-VII in FIG 6, is shown. Here, the ridges 16" and grooves 17" are shown somewhat enlarged. The ridges are shown to be rectangular in cross section. However they could have V-shaped cross-section.

FIG 8 shows an alternative shape of the grooves 17" and ridges 16". Here they are formed in an annular and concentric pattern. Other patterns are also possible, e.g. elliptic or spiral. In Fig 9 a cross section taken at IX-IX in figure 8, is shown. Also here, the ridges 16" and grooves 17" are shown somewhat enlarged. The cross-sectional shapes of the grooves and ridges could be the same as in the embodiment of FIGS 6 and 7.

In the embodiments of the invention above, the first 11", second 12" and third 13" walls are all made of an electrically conductive material that is to be in contact with surrounding tissue. However the third wall 13" could be made of an electrically conductive material, and the second wall 12" and possibly also the first wall 11" made of a non-conductive material, or alternatively covered with an insulating layer.

The curve radii of the irregularities or ridges are very small, at least smaller than 1 mm, and they could be as small as 0.1 mm, or smaller.

Although the invention is described by means of the above examples, naturally, many variations are possible within the scope of the invention.

CLAIMS

1. A housing (1") for an implantable tissue stimulating device, comprising:

- a first wall (11") having a first generally flat exterior surface,
- a second wall (12") having a second generally flat exterior surface, and
- a third circumferential wall (13") joining said first (11") and second (12") wall and comprising a curved circumferential first wall section (14") being connected to said first wall (11"), a curved circumferential second wall section (15") being connected to said second wall (12"),

said housing (1") being connectable to an electrode lead (3") having an electrode, which is adapted to be in contact with a tissue, at a distal end thereof,
characterised in

- the first wall (11") being adapted to face the skin of a patient,
- at least the third wall (13") being made of a conductive material, said conductive material being adapted to be in electrical contact with a surrounding tissue and to serve as an electrode, and
- a curve radius of the first wall section (14") being smaller than a curve radius of the second wall section (15"), for curve radii in planes essentially perpendicular to the first and second surfaces, whereby
- when a voltage is applied between the housing (1") and the electrode an electric field is obtained having lower field strength along the curved second wall section (15") than along the curved first wall section (14").

2. The device according to claim 1, wherein
- the first wall (11") being made of a conductive material, and adapted to be in electrical contact with a surrounding tissue and to serve as an electrode conjointly with the third wall (13").

3. The device according to claim 1 or 2, wherein
- the second wall (12") being made of a conductive material, and adapted to be in electrical contact with a surrounding tissue and to serve as an electrode conjointly with at least the third wall (13").

4. The device according to any preceding claim, wherein
- the first (14") and second (15") wall sections being circularly curved in said planes.

5. The device according to claim 4, wherein
- each of the first (14") and second (15") wall sections have centres of curvature along a continuous first and second curve, respectively.

6. The device according to claim 5, wherein
- the continuous first and second curves are essentially parallel.

7. The device according to any preceding claim, wherein
- the ratio between the curve radii is in the range of 1:2-1:6.

8. The device according to any preceding claim, wherein
- the ratio between the curve radii is about 1:4.

9. The device according to any preceding claim, wherein
- the first exterior surface is rough.

10. The device according to any preceding claim, wherein
- the first exterior surface is contoured.

11. The device according to claim 10, wherein
- the first exterior surface is provided with a plurality of ridges (16").

12. The device according to claim 11, wherein
- each of the ridges (16") is provided with at least one edge being a sharp corner.

13. The device according to any preceding claim, wherein
- the second exterior surface is polished.

Fig. 1

(PRIOR ART)

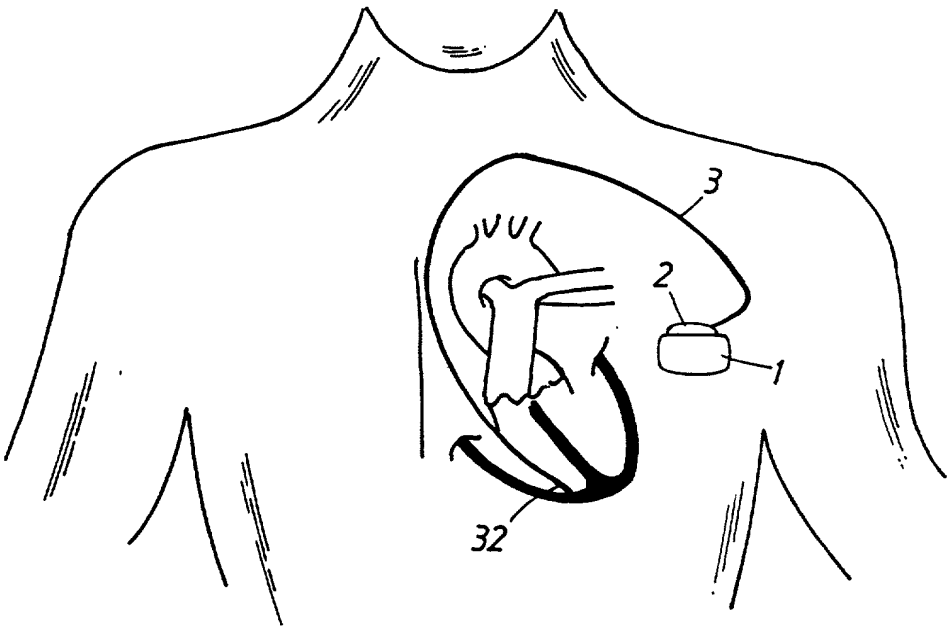


Fig. 2
(PRIOR ART)

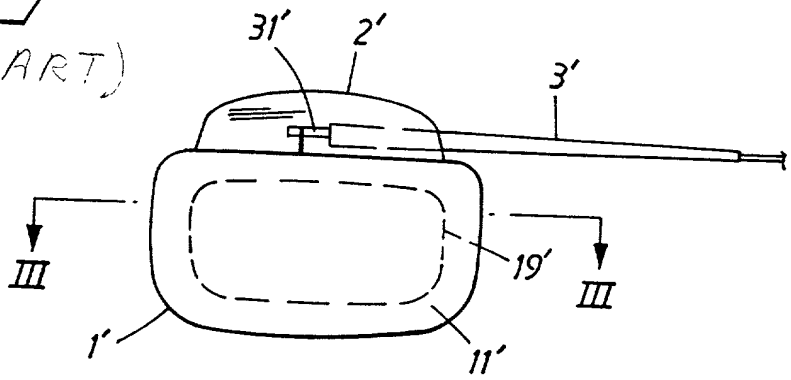


Fig. 3
(PRIOR ART)

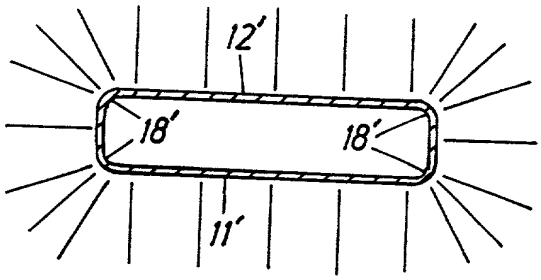


Fig. 4

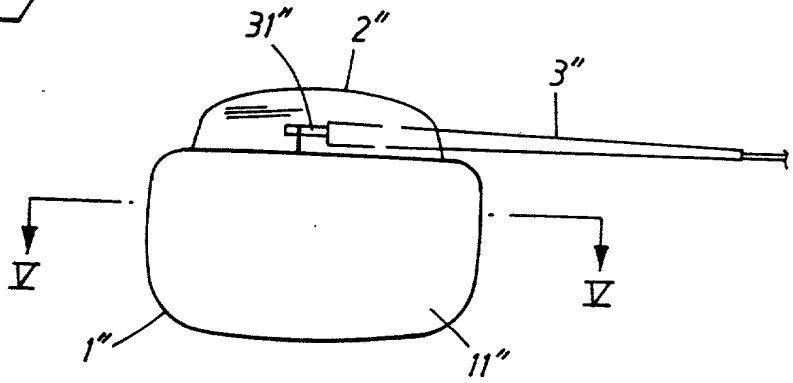


Fig. 5

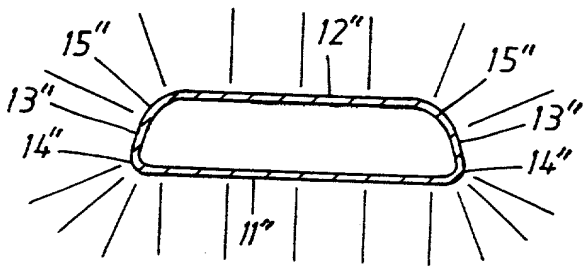


Fig. 6

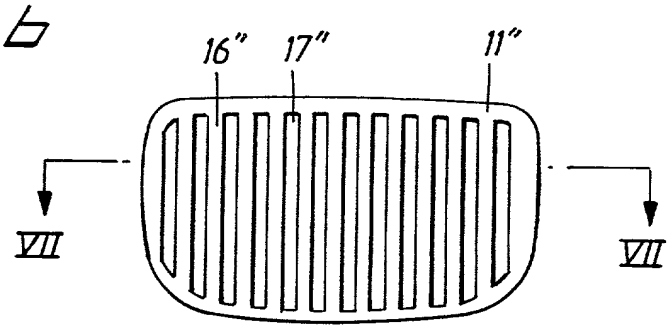


Fig. 7

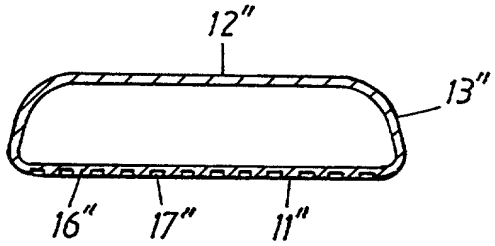


Fig. 8

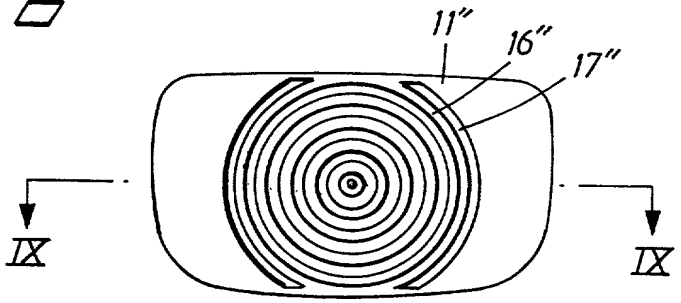
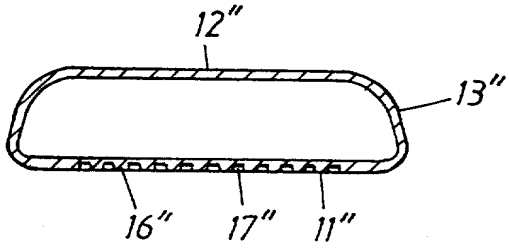


Fig. 9



COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (Includes Reference to PCT International Applications)	ATTORNEY'S DOCKET NUMBER P01,0292

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,
I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

"IMPLANTABLE TISSUE STIMULATING DEVICE"

the specification of which (check only one item below):

☐ is attached hereto.

☐ was filed as United States application
Serial No. _____

on _____,

and was amended

on _____(if applicable).

■ was filed as PCT international application

Number PCT/SE00/00203

on February 1, 2000,

and was amended under PCT Article 19

on _____(if applicable).

I hereby state that I have reviewed and understand the contest of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (If PCT indicate "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
Sweden	9900662-7	25.02.99	■ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO

Combined Declaration For Patent Application and Power of Attorney (Continued) (Includes Reference to PCT International Applications)	ATTORNEY'S DOCKET NO. P01,0292

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT International application(s) designating the United States of America that is/are listed below and, insofar as the subject mater of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occured between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S. APPLICATIONS		STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	PATENTED	PENDING	ABANDONED

PCT APPLICATIONS DESIGNATING THE U.S.

PCT APPLICATION NO	PCT FILING DATE	U.S. SERIAL NUMBERS ASSIGNED (if any)			

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected herewith.

And I hereby appoint all Attorneys identified by the United States Patent & Trademark Office Customer Number 26574, who are all members of the firm of Schiff, Hardin & Waite.

Send Correspondence to:	Direct Telephone Calls to:
SCHIFF, HARDIN & WAITE Patent Department 6600 Floor Sears Tower, Chicago, Illinois 60606 Customer Number 26574	312/258-5790

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	POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY
203	FULL NAME OF INVENTOR	FAMILY NAME	FIRST GIVEN NAME	SECOND GIVEN NAME
	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE & ZIP CODE/COUNTRY

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

SIGNATURE OF INVENTOR 201	SIGNATURE OF INVENTOR 202	SIGNATURE OF INVENTOR 203
DATE Aug 23, 2001	DATE	DATE